

Claims 1 to 35 and 54 to 60 are pending in the present application. No claims have been amended. Claims 36 to 53 have been canceled, without prejudice, and Claims 54 to 60 have been added. The added claims are directed to certain preferred embodiments of the invention that fall within the scope of the previously pending claims of elected Group I, and are described in the specification (*see, e.g.*, Example 64). Accordingly, the addition of these claims does not constitute any new matter.

Applicants thank the Examiner for taking the time to discuss this application with Applicants' representative in a telephonic interview. Applicants acknowledge and appreciate the Examiner's indication during the interview that the error in the election of species in the Response dated December 18, 2001 is of no consequence to the prosecution of this case, since the Examiner has subsequently searched the generic structure defined by Claim 1.

Response to Rejection Under 35 U.S.C § 112:

In the Office Action dated April 23, 2002, Claims 1 to 35 were rejected under 35 U.S.C. § 112, second paragraph. In making this rejection it was asserted that the terms "lower alkyl" and "lower alkylene" rendered the claims vague.

Applicants respectfully submit that the terms are not vague, because they are specifically defined in the specification. As stated at page 22, lines 8 to 9, as used in the instant application, the term "lower alkyl" refers to "an alkyl group having 1 to about 8 carbon atoms." At page 23, lines 11 to 12, it is stated that the term "lower alkylene," as used in the instant application, refers to "an alkylene group having 1 to about 4 carbon atoms." Thus, contrary to the assertions made in the Office Action, it is not unclear how many carbons are contained in a

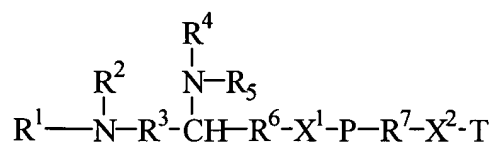
“lower” group. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

Response to Rejection Under 35 U.S.C. § 102

Claims 1 to 5 and 17 to 35 stand rejected under 35 U.S.C. § 102(b) as anticipated by Unger, et al., U.S. Patent No. 5,830,430 (“the 430 patent”). Applicants respectfully traverse this rejection.

It appears from the Office Action that this rejection is based on the fact that the 430 patent discloses, in Example 5C, a cationic lipid compound that is the same compound as described in Example 1 of the instant application. Applicants concede that these two examples describe the same compound. Applicants respectfully note, however, that the compound described by those two examples is NOT within the scope of any claim of the instant specification.¹

Claim 1, the only pending independent claim, defines a compound of Formula IV:



wherein R¹ and R⁴ are each independently *acyl* of from about 7 to about 23 carbons, and R² and R⁵ are each independently hydrogen or lower alkyl. The compound described in Example 5C of the ‘430 patent does not contain nitrogen atoms bearing such groups.

¹ Examples of compounds of Formula IV, as defined in Claim 1, include, *inter alia*, Examples 63 to 65.

Additionally, the formula set forth above further recites the presence of “T”, a targeting ligand which targets cells or receptors selected from the group consisting of myocardial cells, endothelial cells, epithelial cells, tumor cells and the glycoprotein GPIIbIIIa receptor. The 430 patent contains no express teaching of such targeting ligands, or of compounds containing same.

Applicants respectfully assert, therefore, that it is clear that the 430 patent does not anticipate the invention defined by Applicants claims. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) over the 430 patent.

Response to Rejection Under 35 U.S.C. § 103

Claims 1 to 35 stand rejected under 35 U.S.C. § 103 over the 430 patent, in view of Unger, et al., U.S. Patent No. 5,770,222 (“the 222 patent”). Applicants also respectfully traverse this rejection.

As discussed above, although the 430 patent does describe cationic lipids which are also described in the instant specification, the 430 patent does not disclose the compounds defined by Applicants’ claims. The 222 patent has apparently been relied on solely for its teaching of the use of gas-filled liposomes for the targeted delivery of bioactive agents.

Applicants do not dispute this teaching. Clearly, however, the 222 patent fails to teach the use of compositions containing compounds according to Formula IV, as recited in independent Claim 1, for the same reasons as discussed above, with regard to the 430 patent. Thus, the 222 provides nothing that would overcome the deficiencies of the 430 patent, as they relate to the pending claims. Accordingly, Applicants respectfully submit that the PTO has failed to meet its burden

to make a *prima facie* case of obviousness, and respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

Miscellaneous

Applicants note that formal drawings were submitted in this application on June 10, 2002.

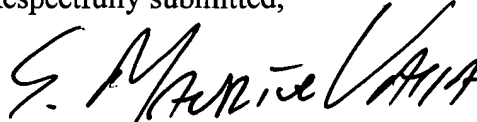
Applicants note that this application contains several amino acid sequences, and thus requires submission of a Sequence Listing, although no communication addressing this matter has been received from the PTO. Accordingly, a separate amendment to add the Sequence Listing, a Statement to Support Filing and Submission in Accordance with 37 C.F.R. §§ 1.821 through 1.825, and both paper and computer readable versions of the Sequence Listing are also being provided at this time.

CONCLUSION

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. An early and favorable reconsideration of the present application, and an allowance of pending Claims 1 to 35 and 54 to 60 are respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Respectfully submitted,

A handwritten signature in black ink, appearing to read "S. Maurice Valla".

S. Maurice Valla

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PATENT

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 36 to 53 have been canceled, without prejudice

Claims 54 to 60 have been added.